

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/027,222

Confirmation No.: 9052

Filed: 20 December 2001

For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

Remarks

The Office Action mailed 27 July 2004 has been received and reviewed. No claims having been amended, and claims 55-63 having been canceled herein, the pending claims are claims 1-42, 44-45, 53-54, and 64-65. Claims 1-38 having been withdrawn from consideration, the claims currently under examination are claims 39-42, 44-45, 53-54, and 64-65. Reconsideration and withdrawal of the rejections are respectfully requested.

Objections to the Claims

The Examiner objected to claims 55-63 under 37 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, claims 55-63 have been canceled, and the rejection has been rendered moot.

Reconsideration and withdrawal of the objection to the claims is respectfully requested.

Provisional Obviousness-Type Double Patenting Rejection

Claims 39-42, 44-45, and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of U.S. Patent Application Serial No. 10/417,609. Claims 39-42 and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of U.S. Patent Application Serial No. 10/272,226 in view of Nelson et al. (U.S. Patent No. 6,344,326). Applicants note that although the Examiner based the second rejection on Application No. 10/272,226, the rejection in the Office Action mailed 6 January 2004 was based on Application No. 10/027,226. In the event the rejection is maintained, clarification is respectfully requested.

Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response. In the event that the provisional

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obviousness-type double patenting rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 39-41, 44-45, and 53-65 under 35 U.S.C. §103(a) as being unpatentable over Nelson (U.S. Patent No. 6,344,326) in view of Gjerde et al. (U.S. Patent No. 6,265,168). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The Amendment and Response submitted by Applicants on 3 October 2003 included remarks (e.g., pages 19-21), which Applicants hereby incorporate by reference in the present response, arguing that both Nelson et al. and Gjerde et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a *surface* comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39).

Specifically, the Examiner asserted that the an anion exchange material partially coated *with a negatively charged polymer* is disclosed at column 30, lines 31-33 of Gjerde et al. Applicants earnestly disagree.

Gjerde et al., recite the following:

The materials used currently in the MIPC column matrix of this invention, as well as other materials suitable for MIPC (as one example, larger polymeric particle sizes of nonporous reverse-phase materials), are known to have an exceptionally

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high capacity and selectivity for long-chain nucleic acids. By applying a suitable pairing ion, and then changing nothing other than the acetonitrile concentration (or any other suitable solvent, such as an alcohol), the quantitative adsorption/desorption of varying lengths of short- and long-chain nucleic acids are essentially turned on and off. Furthermore, since the matrix is made of a nonporous polymeric material, there is no opportunity for interlopers (dNTPs, primers, primer dimers, non-specific amplification products) to get trapped and become problematic downstream. In essence, the matrix materials we possess (nonporous polystyrene-divinylbenzene, either unalkylated or alkylated) are perfectly suited to the purification of PCR products prior to the most demanding molecular biology applications. Also suitable are nonporous polymeric or modified silica materials which has been manufactured or purified in a manner which produces surfaces which are free of contamination. These can be in the form of beads, monoliths, channels, capillary or planar surfaces. *The polymeric surfaces can be provided by non-alkylated and alkylated materials including polystyrene, divinylbenzene, hydroxyethylmethacrylate, and other nonionic polymers.*

(column 30, lines 5-30). Thus, Applicants respectfully submit that Gjerde et al. clearly disclose the use of *nonionic polymers*.

Further, Gjerde et al., at column 30, lines 31-33, explicitly state that "[p]olymers having a negative charge may also be used provided the charged groups are *protonated to produce a neutral surface, i.e., carboxylic acid*" (emphasis added). In other words, Gjerde et al. are disclosing that polymers that initially have a negative charge (e.g., negatively charged carboxylate groups, i.e., -CO_2^- groups) may be used provided that the charged groups are protonated to produce a neutral surface (e.g., uncharged carboxylic acid groups, i.e., $\text{-CO}_2\text{H}$ groups). In short, the recitation at column 30, lines 31-33 of Gjerde et al. reinforces the use of *uncharged (e.g., nonionic) polymers* that can include, for example, uncharged carboxylic acid groups.

Nonetheless, the Examiner stated that "Applicant has used open claim language (comprising) and therefore other features may be present in the cited reference. This would include positively charged groups which may be present to provide the neutral charge" (page 7,

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lines 1-3 of the Office Action mailed 6 January 2004). However, Applicants do not understand the Examiner's intended meaning of this statement. Specifically, the Examiner has failed to point to a disclosure in Gjerde et al. of using a negatively charged polymer and including positively charged groups to provide a neutral charge. In contrast, Gjerde et al. disclose the neutralization of anionic groups (e.g., protonation), as discussed herein above. In the event that this rejection is maintained, clarification of this statement is respectfully requested in the next Official Communication.

Thus, Applicants respectfully reiterate that neither Nelson et al. nor Gjerde et al., either alone or in combination, provide a disclosure or suggestion of using an anion exchange material partially coated with *a negatively charged polymer* (e.g., present independent claim 39). Thus, Nelson et al. in view of Gjerde et al. fail to teach or suggest all the present claim language, and Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness.

The Examiner also rejected claim 42 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,265,168 (Gjerde et al.) as applied above, and further in view of U.S. Pat. No. 6,319,469 (Mian et al.). Applicants respectfully traverse the rejection.

Claim 42 depends from independent claim 39. Applicants respectfully submit that Mian et al. provide nothing to correct the deficiencies of Nelson et al. in view of Gjerde et al. Thus, Applicants respectfully submit that claim 42 is patentable for at least the reasons presented herein above for the patentability of independent claim 39, in addition to the subject matter recited therein.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

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Request for Rejoinder

Claims 1-38 recite methods of using a device as recited, for example, in claim 39. Specifically, independent claims 1-2, 17-18, 20-21, and 36 recite language from independent claim 39. Upon an indication of claim 39 being allowable, Applicants respectfully request that the method claims (e.g., claims 1-38) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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September 27, 2004
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27th day of September, 2004, at 3:15 p.m. (Central Time).

By: [Signature]
Name: Rachel Baglioni-Orban